UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,199	05/31/2001	Jean-Charles Schwartz	P06853US00/L	8229

881 7590 05/08/2003

LARSON & TAYLOR, PLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA, VA 22314

EXAMINER
SEAMAN, D MARGARET M

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/622,199	Applicant(s) SCHWARTZ ET AL.	
	Examin r D. Margaret Seaman	Art Unit 1625	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-126* is/are pending in the application.

4a) Of the above claim(s) *123* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-122 and 124-126* is/are rejected.

7)☒ Claim(s) *126* is/are objected to.

8)☒ Claim(s) *89-126* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This application was filed 31 May 2001 and is a 371 of PCT/EP99/05744, filed 29 July 1999. New claims 124-126 were added by paper #17. Claims 89-126 are before the Examiner. A lack of unity of invention remains in effect. The originally elected group II was drawn to compounds and methods of use of compounds of formula (IIa). Due to this, the new group I will be the elected and examined group. The lack of unity of invention/restriction was made final in paper #9, dated 18 October 2001. The finality of the office action of paper #19, dated 9 April 2003, is withdrawn. The time for response has been reset with the date of this office action.

Election/Restrictions

2. As stated in paper #6, dated 6 September 2001, restriction is required under 35 U.S.C. 121 and 372. The original groups have been brought down to the following two groups due to applicant's cancellation of claims 1-88 and insertion of new claims 89-123 in paper #11.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 89-122 and new claims 124-126, drawn to methods of treatment of compounds of formula (IIa), classified in various classes and subclasses.

II. Claim 123, drawn to methods of treatment of compounds of formula (A), classified in various classes and subclasses.

37 CFR 1.475. Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application

and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

3. As stated in paper #9, dated 18 October 2001:

The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common core between all of these groups is "N". This is not a special technical feature that forms a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. However, it is not seen where N is a contribution over the prior art.

4. Applicant's election with traverse of group II in Paper No. 8, dated 9 October 2001, is acknowledged. The traversal is on the ground(s) that the instant claims have unity of invention due to the special technical feature of W. This is not found persuasive because of the following: A common core is something that is the same between all members of the Markush grouping. W is defined as a residue which has activity when attached to an imidazole grouping. Well, W is not attached to an imidazole grouping due to the confines of claim 1. There is no teaching in the specification of how to determine if something has activity as a residue. If such is not taught, then it is part of the common knowledge. Common knowledge is not a contribution over the prior art. Therefore, W cannot be a special technical feature.

The requirement is still deemed proper and is therefore made *FINAL*.

4. The instant group I corresponds to the previously elected group II, group I will be examined. Claim 123 has been withdrawn from consideration as being drawn to a non-elected group II.

5. This application contains claim 123, drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. The restriction/lack of unity of invention was made final in paper #9.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 89-122 and now new claims 124-126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 89 has the ambiguous language and the remaining claims are dependent from claim 89.

Specifically, the claims are ambiguous due to many things in claim 89. The remaining claims are dependent from claim 89. Claim 89 is ambiguous due to the newly added language. The claim is drawn to a method of treating diseases or

conditions selected from the group consisting of (1) treating central nervous system disorders, (2) providing psychotropic effects, promoting wakefulness attention, memory and improving mood, etc. The claim should read "A method of treating diseases or conditions selected from the group consisting of obesity, vertigo, motion sickness, etc. A method of treatment does not include providing sedative tranquilizing antistress, analgesic and antimigrane activity. These are descriptions of what can be done but not diseases or conditions that are treated. Also, the claim contains "including" in line 8 of the claim.

Claims 125 and 126 are ambiguous due to the claims being drawn to a method of treating wherein the CNS disorders treated are selected from many diseases including obesity. How is obesity a CNS disorder? Clarification is required.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 89-122 and new claims 124-126 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, it is not seen where the instant specification enables the ordinary artisan to use the instant invention

to treat central nervous system disorders, providing psychotropic effects, providing nootropic effects, treating psychosomatic disorders and other conditions such as obesity. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims: The claims are drawn to a method of treatment of many diseases and conditions somehow linked to the ligand of the histamine H3 receptors by using a multitude of compounds having a nitrogen atom as a core.

2) The nature of the invention: The treatment of diseases/conditions linked to the ligand of histamine H3 receptors.

3) The state of the prior art: The prior art does not link all the diseases/conditions listed in the claims to a ligand of the histamine H3 receptors.

5) The level of predictability in the art: The predictability in the art is low due to the large differences in the activities of the compounds tested.

6) The amount of direction provided by the inventor: There is little direction provided by the inventor other than the specific examples in the specification.

7) The existence of working examples: There are many example compounds in the specification, however, few have been shown as having activity. Of those compounds tested, the activities vary widely with only minor changes in structure.

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The amount of experimentation needed is large due to the little guidance provided by the specification.

Taking all of this into consideration, the specification is not seen to be enabling.

10. Applicant has provided a declaration (paper #18, dated 22 November 2002) disclosing how compound 117, 3-(4-chlorophenyl)propyl-3-piperidinopropyl ether, changes tele-methylhistamine levels. This declaration is not commensurate in scope for the instant claims 89-122 and 124-126. This declaration enables the one compound #117 to treat diseases and conditions by changing the tele-methylhistamine levels in a patient in need thereof. However, this is not seen as enabling for any and all compounds that are encompassed by the instantly claimed compounds. Also, this declaration does not enable the connection between tele-methylhistamine levels and the diseases and conditions listed in the instant claims. A claim that is limited to the compound of #117 and limited to changing the levels of tele-methylhistamine, having proper support

under 35USC 101, would be seen as allowable. All other claims remain as lacking enablement.

Double Patenting

11. Claim 126 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 125. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The claim 126 is a word-for-word duplicate of claim 125.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 703-308-4528. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

D. Margaret Seaman
Primary Examiner
Art Unit 1625

dms
May 2, 2003